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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,814	02/28/2002	Tatjana Dragic	61010-AB-1/IPW/MAF/DJK	1614

7590 04/22/2004

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EXAMINER

TELLER, ROY R

ART UNIT PAPER NUMBER

1654

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,814	DRAGIC ET AL.	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 32-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0404</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This office action is in response to the restriction/election, received 2/5/04, in which applicant elected group I, claims 1-31, with traverse. The Applicant contends that groups I-III, claims 1-63 are not independent inventions, that there is a disclosed relationship between the subject matter claimed and that there would not be a serious burden on the Examiner if restriction were not required. This is not found persuasive because the inventions of groups I-III are distinct, as evidenced by their different functions as pointed out in the restriction requirement, further, the Examiner contends that the search for each of the inventions of groups I-III is not co-extensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious the other group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine the three inventions in one application.

The requirement is still deemed proper and is therefore made FINAL.

Claims 32-66 are withdrawn as being drawn to non-elected inventions.

Claims 1-31 are pending.

Information Disclosure Statement

The information disclosure statement filed 1/27/03 is acknowledged. A signed copy is attached hereto.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptides S-10/14 and S-3/10/14 does not reasonably provide enablement for the compound comprising the structure: alpha-Y-D-I-N-Y-Y-T-S-beta wherein alpha represents from 0 to 9 amino acids; wherein beta represents from 0 to 14 amino acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

With respect to the elected invention, Applicants have reasonably demonstrated that peptides S-10/14 and S-3/10/14 inhibit binding of gp 120 jr-fl/ CD4-IgG2 complex to CCR5+ cells in a dose dependent manner and that peptides S-10/14 and S-3/10/14 inhibited the entry of the R5 isolate HIV-1 jr-fl by approximately 50% in HeLa-CD4+CCR5+ and U87MG-CD4+CCR5+ as evidenced by figure 1a and figure 5 of the instant specification. However, the claims broadly encompass a group of amino acid configurations which are clearly beyond the scope of the instant disclosure.

Accordingly, with respect to the elected invention, others skilled in the art would be unable to practice the invention as claimed without undue experimentation and with a reasonable expectation of success, other than using peptides S-10/14 and S-3/10/14 as evidenced by figure 1a and figure 5 of the instant application.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-31 are rejected under 35 U.S.C. 102(a) as being anticipated by Cormier et al. (PNAS, 2000, vol. 97, No. 11, pp-5762-5767).

The instant invention is drawn to a compound comprising the structure: alpha-Y-D-I-N-Y-Y-T-S-beta wherein alpha represents from 0 to 9 amino acids; wherein beta represents from 0 to 14 amino acids, wherein an amount of the compound effectively inhibits binding of HIV-1 to a CCR5 receptor on the surface of a CD4+ cell.

Cormier teaches inhibition of gp120/CD4 binding to CCR5 by Nt peptides, wherein peptides S-3/10/14 and S-10/14 inhibited complex binding to cells in a dose dependent manner, see page 5763 and figure 1a, page 5764. Cormier discloses inhibition of HIV-1 entry by CCR5 Nt peptides, in which only peptides S-10/14 and S-3/10/14 inhibited the entry of the R5 isolate HIV-1 jr-fl by approximately 50% in HeLa-CD4+CCR5+ and U87MG-CD4+CCR5+, see page 5764 and figure 5, page 5766.

Accordingly, the cited reference is deemed to anticipate the above claims.

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Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (571) 272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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4/16/04

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CHRISTOPHER R. TATE
PRIMARY EXAMINER